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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
|-----------------|-------------|----------------------|---------------------|------------------|

10/540,756

06/24/2005

Jean-Pierre Cougoulic

0561-1036

7167

466 7590 07/09/2010

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EXAMINER

PEPITONE, MICHAEL F

ART UNIT

PAPER NUMBER

1796

NOTIFICATION DATE

DELIVERY MODE

07/09/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DocketingDept@young-thompson.com

| | | | |
|------------------------------|--------------------------------------|---|--|
| Office Action Summary | Application No. 10/540,756 | Applicant(s) COUGOULIC, JEAN-PIERRE | |
| | Examiner MICHAEL PEPITONE | Art Unit 1796 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 April 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-28,36 and 41-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-28,36 and 41-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 28, 46, 41, and 43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 28, 46, 41, and 43: The phrase “in order of performance” in claims 28 and 41 is vague and indefinite as to what is encompassed by the phrase. It is unclear if said phrase refers the specific order of baths as listed in the claims, or a certain sequence which yields the best result. The metes and bounds of the scope of the invention are unclear. For the purpose of examination, the specific order of baths listed in the claims will be used.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 1796

Claims 21-24, 26-27, and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cougoulic (US 5,872,159) in view of Mills *et al.* (US 6,482,584).

Regarding claims 21-22: Cougoulic teaches a material for medical or veterinary use designed for the execution of endo-bone implants, bone prostheses, and dental implants (1:5-12), wherein the material is in the form of a molded part made of a biocompatible thermoplastic polymer {binder} containing at least one compound for adding calcium or phosphorous (1:35-62; 2:56-60; 3:20-4:20), wherein the material comprises a thermoplastic polymer in an amount of at least 65 weight% of the composition and contains 10-35 weight% of chemical components designed for fostering biological integration, such as tricalcium phosphate, calcium hydroxyapatite [instant claim 22] (1:55-2:3; 2:61-3:14). Cougoulic teaches molding operations (2:56-60; 3:1-8; 4:13-48). Cougoulic teaches a specific material {mixture 5} comprising 80 wt% polyetheretherketone (PEEK), 10 wt% tricalcium phosphate ($\text{Ca}_3(\text{PO}_4)_2$), and 10 wt% titanium dioxide (TiO_2) (4:2-5).

Cougoulic does not teach surface pickling or decontamination operations on the molded material. However, Mills *et al.* teaches a method of cleaning/sterilizing implants, as well sterile packaging of the implant (1:5-14; 3:65-4:11; 14:34-55), comprising subjecting the implant to an oscillation of pressure in the presence of various cleaning solutions in a chamber which can undergo {elevated} temperature and pressure cycles {autoclave} (4:14-65), wherein the chamber permits sonication of the contents (4:52-54; 6:49-58; 8:14-51). The surface treatment includes solutions of: HCl (14:5-21, Table II (J)), acetone (14:5-21, Table II (J)); hydrogen peroxide (4:14-18), sodium hypochlorite (14:5-12), Betadine or isopropanol {decontaminating product}(4:14-18; 14:5-21), and sterile water (11:28-33, Tables I and II) [i.e. a process of

Art Unit: 1796

pressure cycling or oscillation, employing a variety of cleaning and sterilization solutions (8:15-51, Tables I-II) {sterilization via autoclave} with concurrent ultrasonic bombardment {surface pickling}, wherein the process steps can be repeated (4:35-37; 8:44-46), and the cleaning fluid is removed to waste under positive pressure and the implant is rinsed under positive pressure and the rinse fluid is removed under positive pressure (11:24-35); subsequently the implant material is packaged in a sterile environment (14:33-55)]. Cougoulic and Mills *et al.* are analogous art because they are concerned with a similar technical difficulty, namely the preparation medical (bone and dental) implants. At the time of invention a person of ordinary skill in the art would have found it obvious to have combined subjecting the implant to an oscillation of pressure in the presence of various cleaning solutions in a chamber which permits sonication of the contents {surface pickling}, as taught by Mills *et al.* in the invention of Cougoulic, and would have been motivated to do so since Mills *et al.* suggests that such processes provide penetrating sterilization of the implant (4: 65-5:14; 8:14-51).

The Office realizes that all the claimed effects or physical properties are not positively stated by the reference. However, the reference teaches all of the claimed reagents and prepared under similar conditions. Therefore, the claimed effects and physical properties, i.e. a surface with emerging crystallized calcium phosphate that is resorbable after implantation to insure an efficient biocompatibility in terms of biological acceptance [instant claim 21], would implicitly be achieved by a composition with all the claimed ingredients. If it is the applicants' position that this would not be the case: (1) evidence would need to be presented to support applicant's position; and (2) it would be the Office's position that the application contains inadequate

Art Unit: 1796

disclosure that there is no teaching as to how to obtain the claimed properties and effects with only the claimed ingredients.

Regarding claims 23-24: Cougoulic teaches the binder is a thermoplastic polymer [instant claim 23], specifically polyetheretherketone (PEEK) [instant claim 24] (2:23-43).

Regarding claim 26: Cougoulic teaches TiO_2 (2:44-50).

Regarding claim 27: Cougoulic teaches chemical components designed for fostering biological integration, such as tricalcium phosphate, calcium hydroxyapatite, and metallic oxide (TiO_2) (2:61-3:14).

Regarding claim 42: Cougoulic teaches injection molding the material (4:37-48).

Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cougoulic (US Patent 5,872,159) in view of Mills *et al.* (US 6,482,584), as applied to claim 21 above, and in further view of Ellingsen *et al.* (US 2002/0111694).

Regarding claim 25: Cougoulic and Mills *et al.* renders the basic claimed composition obvious [as set forth above with respect to claim 21].

Cougoulic does not teach cellulose as a binder. However, Ellingsen *et al.* teaches medical prosthetic devices and implants (bone and dental) comprising cellulose as a biopolymer (§ 2, 9, and 19). Cougoulic and Ellingsen *et al.* are analogous art because they are concerned with a similar technical difficulty, namely the preparation medical (bone and dental) implants. At the time of invention a person of ordinary skill in the art would have found it obvious to have combined cellulose, as taught by Ellingsen *et al.* in the invention of Cougoulic, and would have been motivated to do so since Ellingsen *et al.* suggests that cellulose provides tissue resilience, strength, rigidity, and integrity of the extra-cellular matrix (§ 21).

Allowable Subject Matter

Claims 28, 36, 41, and 43 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.

The following is a statement of reasons for the indication of allowable subject matter: While Cougoulic (US '159) disclose a specific injection molded material {mixture 5; 4:2-5} comprising 80 wt% polyetheretherketone (PEEK), 10 wt% tricalcium phosphate ($\text{Ca}_3(\text{PO}_4)_2$), and 10 wt% titanium dioxide (TiO_2) (4:2-5; 4:37-48), and Mills *et al.* (US '584) generally disclose subjecting implants to an oscillation of pressure in the presence of various cleaning solutions in a chamber which permits sonication of the contents {surface pickling} (4: 65-5:14; 8:14-51), the combination of the references fails to disclose the claimed process steps {claims 28 and 41} with sufficient specificity to afford a medical material having a surface provided with crystallized calcium phosphate.

Response to Arguments

Applicant's arguments filed 4/6/10 have been fully considered but they are not persuasive. The rejection of claims 21-24, 26-27, and 42 based upon Cougoulic (US 5,872,159) and Mills *et al.* (US 6,482,584) is maintained for reason of record and the following response.

Cougoulic (US '159) disclose a specific material {mixture 5} comprising 80 wt% polyetheretherketone (PEEK), 10 wt% tricalcium phosphate ($\text{Ca}_3(\text{PO}_4)_2$), and 10 wt% titanium dioxide (TiO_2) (4:2-5), wherein the material is injection molded (4:37-48).

Art Unit: 1796

Mills *et al.* (US '584) disclose subjecting implants to an oscillation of pressure in the presence of various cleaning solutions in a chamber which permits sonication of the contents {surface pickling}; as such processes provide penetrating sterilization of the implant (4: 65-5:14; 8:14-51).

The examiner maintains the position that the combined teaching of Cougoulic (US '159) {material comprising 80 wt% PEEK, 10 wt% $\text{Ca}_3(\text{PO}_4)_2$, and 10 wt% TiO_2 (4:2-5)} and Mills *et al.* (US '584) {cleaning/sterilizing implants via oscillation of pressure in the presence of various cleaning solutions in a chamber which permits sonication of the contents {surface pickling}} would afford an implant having a surface with emerging crystallized calcium phosphate that is resorbable after implantation to insure an efficient biocompatibility in terms of biological acceptance. If it is the applicants' position that this would not be the case, evidence {data} would need to be presented to support applicant's position. Additionally, evidence would need to be provided for a showing of unexpected results and the prior art of record.

In response to applicant's argument that the claimed material contains a surface with emerging crystallized calcium phosphate that is resorbable after implantation to insure an efficient biocompatibility in terms of biological acceptance, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art (i.e. penetrating sterilization of the implant {surface pickling}) cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

Regarding applicant's arguments that the combination of acetone with ultrasonication etches a layer of the binder without etching the osteo-inductive compounds {see applicant's

Art Unit: 1796

remarks, pg. 10, ln. 8-17}; the examiner notes claim 21 fails to recite such steps. As a result, applicant's arguments are broader than the claimed material of claim 21, since the combined teaching of Cougoulic (US '159) {material comprising 80 wt% PEEK, 10 wt% $\text{Ca}_3(\text{PO}_4)_2$, and 10 wt% TiO_2 } and Mills *et al.* (US '584) {cleaning/sterilizing implants via oscillation of pressure in the presence of various cleaning solutions in a chamber which permits sonication of the contents {surface pickling}} would afford an implant having a surface with emerging crystallized calcium phosphate that is resorbable after implantation to insure an efficient biocompatibility in terms of biological acceptance. Applicant has failed to provide evidence that the cleaning/sterilizing of implants {surface pickling} procedure of Mills *et al.* (US '584) employed on the molded implant material of Cougoulic (US '159) {material comprising 80 wt% PEEK, 10 wt% $\text{Ca}_3(\text{PO}_4)_2$, and 10 wt% TiO_2 } does not afford the claimed material having a surface provided with emerging crystallized calcium phosphate.

The rejection of claim 25 based upon Cougoulic (US 5,872,159), Mills *et al.* (US 6,482,584), and Ellingsen *et al.* (US 2002/0111694) is maintained for reason of record and the following response.

Applicants' arguments regarding Cougoulic (US '159) and Mills *et al.* (US '584) have been sufficiently addressed above. Ellingsen *et al.* (US '694) was relied on for disclosing medical prosthetic devices and implants (bone and dental) comprising cellulose as a biopolymer (§ 2, 9, and 19).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Pepitone whose telephone number is 571-270-3299. The examiner can normally be reached on M-F, 7:30-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Eashoo can be reached on 571-272-1197. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1796

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MFP
28-June-10

/Mark Eashoo/
Supervisory Patent Examiner, Art Unit 1796